

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION**

SYLVIA WINGARD as the Administrator)
of the Estate of GEORGE WINGARD,)

Plaintiff,)

v.)

PFIZER INC., a Delaware)
Corporation; PHARMACIA)
CORPORATION, a Delaware Corporation;)
MONSANTO, COMPANY, a Delaware)
Corporation; G.D. SEARLE, LLC.,)
a Delaware Corporation; ALEX)
DUMOULIN, JR and fictitious Defendants)
A, B, C and D being those persons, firms)
or corporations whose actions, inactions,)
fraudulent suppression, fraud, scheme)
to defraud and/or other wrongful conduct)
caused or contributed to the Plaintiff's)
injuries and damages, and whose true)
names and identities are presently unknown)
to the Plaintiff but will be substituted by)
amendment when ascertained,)

Defendants.)

CIVIL ACTION NO:

2:06CV254-D

RECEIVED
MAR 17 2006
FBI - MONTGOMERY

2006 MAR 17 P 8:36

RECEIVED

**ANSWER AND DEFENSES OF ANSWERING DEFENDANTS TO
PLAINTIFF'S COMPLAINT**

Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia" and also improperly captioned in Plaintiff's complaint as Monsanto Company), G.D. Searle LLC ("Searle") (improperly captioned in Plaintiffs' Complaint as "G.D.

Searle, LLC”), and Alex Dumoulin, Jr. (“Dumoulin”) (collectively the “Answering Defendants”) hereby answer Plaintiff’s Complaint in this action and state as follows:

PRELIMINARY STATEMENT

The Complaint does not state when Plaintiff’s decedent was prescribed or used Bextra® and, as such, this Answer can only be drafted generally and without reference to a specific period in time. Answering Defendants reserve the right to amend this Answer if or when discovery reveals the time period in which the Plaintiff’s decedent was prescribed and used Bextra®.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of Plaintiff’s Complaint.

**ANSWERING:
STATEMENT OF THE PARTIES**

1. Answering Defendants deny that Plaintiff’s decedent’s injuries resulted from his alleged use of Bextra® (Valdecoxib). As for the remainder of the allegations contained therein, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in Paragraph 1, and therefore deny the same.

2. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in Paragraph 2, and therefore deny the same.

3. Answering Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia Corporation, which is in turn a wholly-owned subsidiary of Pfizer. Searle is a Delaware limited liability company with its principal place of business in Illinois and that it is registered to do business in Alabama. Answering Defendants admit that, during certain period(s) of time, Searle has manufactured, marketed, sold and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Answering Defendants state the allegation in paragraph 3 of Plaintiff's complaint regarding place of service is a legal conclusion to which no response is required. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 3.

4. Answering Defendants admit that Pharmacia is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey, and is registered to do business in Alabama. Answering Defendants admit that, during certain period(s) of time, Pharmacia marketed the prescription drug Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Answering Defendants

state the allegation in paragraph 4 of Plaintiff's Complaint regarding place of service is a legal conclusion to which no response is required. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 4.

5. Answering Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold, or distributed Bextra®, the Defendants are, therefore, stating that the 2000 Monsanto is not a proper party in this matter. Except as admitted herein, Defendants deny the allegations of Paragraph 5.

6. Answering Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and is registered to do business in Alabama. Answering Defendants admit that, during certain period(s) of time,

Pfizer marketed, distributed and sold Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Answering Defendants state the allegation in paragraph 6 of Plaintiff's Complaint regarding place of service is a legal conclusion to which no response is required. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 6.

7. Answering Paragraph 7, Answering Defendants admit that Alex Dumoulin, is a sales representative for Pfizer. Answering Defendants state that the allegation in Paragraph 7 of Plaintiff's Complaint regarding place of service is a legal conclusion to which no response is required. Except as admitted herein, Answering Defendants deny the allegations of Paragraph 7.

8. This paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained in this paragraph.

9. Answering Paragraph 9, Answering Defendants lack sufficient knowledge and information as to facts concerning the citizenship of Plaintiff and the amount in controversy to form a belief as to the truth of the jurisdictional allegations contained therein, and therefore deny the same. By way of further answer, Answering Defendants state that Paragraph 9 of the Complaint contains

legal conclusions to which no answer is required. Except as stated herein, Answering Defendants further deny the allegations contained therein.

10. Answering Defendants deny the allegations contained in this paragraph.

11. Answering Defendants deny the allegations contained in this paragraph.

12. Answering Defendants deny the allegations contained in this paragraph.

13. Answering Defendants are without sufficient information to admit or deny the allegations contained in this paragraph, and therefore deny the same.

14. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
STATEMENT OF THE FACTS**

15. Answering Defendants admit that, during certain period(s) of time, Searle has manufactured, marketed, sold and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Answering Defendants admit that, during certain period(s) of time, Pharmacia marketed the prescription drug Bextra® in the United States for the indications set forth in the

FDA-approved package inserts and as permitted by law. Answering Defendants admit that, during certain period(s) of time, Pfizer marketed, distributed and sold Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations contained in this paragraph.

16. Answering Paragraph 16, Answering Defendants state that Bextra is a prescription medication which at all times relevant to this suit was approved by the FDA for use consistent with its prescribing information. Answering Defendants admit that at times they manufactured, marketed and distributed Bextra in the United States to be prescribed by healthcare providers who are authorized by law to prescribe medications in accordance with their approval by the FDA. Except as stated herein, Answering Defendants deny the allegations contained in Paragraph 16.

17. Answering Defendants deny the allegations contained in this paragraph.

18. Answering Defendants are without sufficient information to admit or deny the allegations contained in this paragraph.

19. This Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants are

without sufficient information or knowledge to admit or deny the allegations regarding Plaintiff's decedent's use of Bextra, and therefore deny the same.

20. Answering Defendants deny the allegations contained in this paragraph.

21. Answering Defendants deny the allegations contained in this paragraph.

22. This paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained therein.

**ANSWERING:
COUNT I:
NEGLIGENCE**

23. Answering Paragraph 23, Answering Defendants incorporate their responses to Paragraphs 1-22 as if set forth fully herein.

24. Answering Defendants deny the allegations contained in this paragraph.

25. Answering Defendants state that these allegations are conclusions of law and hence no response is required. To the extent a response is deemed required, Answering Defendants admit that they had duties as are imposed by law. Answering Defendants deny the remaining allegations contained in this paragraph.

26. Answering Defendants deny every allegation of this paragraph and all subparts thereto.

27. Answering Defendants deny the allegations of this paragraph.

28. Answering Defendants deny the allegations of this paragraph.

29. Answering Defendants deny the allegations of this paragraph.

30. Answering Defendants deny the allegations of this paragraph.

31. Answering Defendants deny the allegations of this paragraph.

**ANSWERING:
COUNT III:
STRICT PRODUCTS LIABILITY/DEFECTIVE DESIGN**

32. Answering Paragraph 32, Answering Defendants incorporate their responses to Paragraphs 1-31 as if set forth fully herein.

33. Answering Defendants deny the allegations contained in this paragraph.

34. Answering Defendants deny the allegations contained in this paragraph and all subparts thereof.

35. Answering Defendants deny the allegations contained in this paragraph.

36. Answering Defendants are without sufficient information or knowledge to admit or deny the allegations contained in this Paragraph, and therefore deny the same.

37. Answering Defendants deny the allegations contained in this paragraph.

38. Answering Defendants deny the allegations contained in this paragraph.

39. Answering Defendants deny the allegations contained in this paragraph.

40. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT III:
STRICT PRODUCTS LIABILITY/FAILURE TO WARN**

41. Answering Paragraph 41, Answering Defendants incorporate their responses to Paragraphs 1-40 as if set forth fully herein.

42. Answering Defendants deny the allegations contained in this paragraph.

43. Answering Defendants are without sufficient information or knowledge to admit or deny the allegations contained in this Paragraph, and therefore deny the same.

44. Answering Defendants are without sufficient information or knowledge to admit or deny the allegations contained in this Paragraph, and therefore deny the same.

45. Paragraph 45 contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they had duties as are imposed by law. Except as admitted herein, Answering Defendants deny the remaining allegations contained in this paragraph.

46. Answering Defendants deny the allegations contained in this paragraph.

47. Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Answering Defendants admit that they had duties as are imposed by law. Answering Defendants deny the remaining allegations of Paragraph 47.

48. Answering Defendants deny the allegations contained in this paragraph.

49. Answering Defendants deny the allegations contained in this paragraph.

50. Answering Defendants deny the allegations contained in this paragraph.

51. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT IV:**

BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

52. Answering Paragraph 52, Answering Defendants incorporate their responses to Paragraphs 1-51 as if set forth fully herein.

53. Answering Defendants deny the allegations contained in this paragraph.

54. Answering Defendants deny the allegations contained in this paragraph.

55. Answering Defendants deny the allegations contained in this paragraph.

56. Answering Defendants deny the allegations contained in this paragraph.

57. Answering Defendants deny the allegations contained in this paragraph.

58. No response is required to this paragraph. To the extent a response is deemed required, Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT V:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

59. Answering Paragraph 59, Answering Defendants incorporate their responses to Paragraphs 1-58 as if set forth fully herein.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained in this paragraph.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained in this paragraph.

62. Answering Defendants deny the allegations contained in this paragraph.

63. Answering Defendants are without sufficient information to admit or deny the allegations contained in this paragraph regarding Plaintiff's decedent's use of Bextra, and therefore deny the same. Answering Defendants deny the remaining allegations contained therein.

64. Answering Defendants deny the allegations contained in this paragraph.

65. Answering Defendants deny the allegations contained in this paragraph and all subparts thereto.

66. Answering Defendants deny the allegations contained in this paragraph.

67. Answering Defendants deny the allegations contained in this paragraph.

68. Answering Defendants deny the allegations contained in this paragraph.

69. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT VI:
FRAUD**

70. Answering Paragraph 70, Answering Defendants incorporate their responses to Paragraphs 1-69 as if set forth fully herein.

71. Answering Defendants deny the allegations contained in this paragraph.

72. Answering Defendants deny the allegations contained in this paragraph.

73. Answering Defendants deny the allegations contained in this paragraph.

74. Answering Defendants deny the allegations contained in this paragraph.

75. Answering Defendants deny the allegations contained in this paragraph.

76. Answering Defendants deny the allegations contained in this paragraph and all subparts thereto.

77. Answering Defendants deny the allegations contained in this paragraph.

78. Answering Defendants deny the allegations contained in this paragraph.

79. Answering Defendants are without sufficient information to admit or deny the allegations contained in this paragraph regarding Plaintiff's use of Bextra, and therefore deny the same. Answering Defendants deny the remaining allegations contained therein.

80. Answering Defendants deny the allegations contained in this paragraph.

81. Answering Defendants deny the allegations contained in this paragraph.

82. Answering Defendants deny the allegations contained in this paragraph.

83. Answering Defendants deny the allegations contained in this paragraph.

84. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT VII:
NEGLIGENT MISREPRESENTATION**

85. Answering Paragraph 85, Answering Defendants incorporate their responses to Paragraphs 1-84 as if set forth fully herein.

86. Answering Defendants deny the allegations contained in this paragraph.

87. Answering Defendants deny the allegations contained in this paragraph.

88. Answering Defendants deny the allegations contained in this paragraph.

89. Answering Defendants deny the allegations contained in this paragraph.

90. Answering Defendants deny the allegations contained in this paragraph.

91. Answering Defendants deny the allegations contained in this paragraph and all subparts thereto.

92. Answering Defendants deny the allegations contained in this paragraph.

93. This paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants

admit that they had duties as are imposed by law. Answering Defendants deny the remaining allegations of this paragraph.

94. Answering Defendants deny the allegations contained in this paragraph.

95. Answering Defendants deny the allegations contained in this paragraph.

96. Answering Defendants deny the allegations contained in this paragraph.

97. Answering Defendants deny the allegations contained in this paragraph.

98. Answering Defendants deny the allegations contained in this paragraph.

99. Answering Defendants deny the allegations contained in this paragraph.

**ANSWERING:
COUNT VIII:
WRONGFUL DEATH**

100. Answering Paragraph 100, Answering Defendants incorporate by reference their responses to Paragraphs 1-99 as if fully restated herein.

101. This paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations of this paragraph.

102. Answering Defendants deny the allegations contained in this paragraph.

103. Answering Defendants deny the allegations contained in this paragraph.

104. No response is required. To the extent a response is deemed required, Answering Defendants deny any wrongdoing.

**ANSWERING:
DEMAND FOR RELIEF**

Answering Defendants deny that the Plaintiffs and Plaintiffs' decedent are entitled to any of the relief demanded in the unnumbered WHEREFORE clause.

DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Answering Defendants in this matter. Answering Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Answering Defendants will withdraw any of these defenses as may be appropriate.

1. Plaintiffs' Complaint fails to state a claim against Answering Defendants upon which relief can be granted.

2. Plaintiffs' claims are barred by the applicable statute of limitations and/or repose or by the equitable doctrines of laches, waiver and estoppel.

3. Plaintiffs' and Plaintiffs' decedent's injuries and damages, if any, were solely caused by the acts or omissions, abuse or misuse, negligence or fault or otherwise, of third persons or parties over whom Answering Defendants had no control or right to control and whose actions are not, therefore, imputable to Answering Defendants.

4. Answering Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiffs or Plaintiffs' decedent herein. Additionally, as a manufacturer and not a seller, Answering Defendants are not subject to liability for implied warranties without privity, i.e., proof of direct and specific transactions between Plaintiffs/Plaintiff's decedent and Answering Defendants. If any such warranties were made, whether express or implied, which Answering Defendants specifically deny, then Plaintiffs and Plaintiff's decedent failed to give timely notice of any breach thereof as required under Ala. Code § 7-2-607.

5. Plaintiffs' and Plaintiff's decedent's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiffs or Plaintiff's

decedent or those acting at the direction or control of Plaintiffs or Plaintiff's decedent, whose contributory negligence or fault is sufficient to bar any recovery by Plaintiffs and Plaintiff's decedent.

6. Plaintiffs' and Plaintiff's decedent's injuries, if any, were due to an unforeseeable idiosyncratic reaction of Plaintiffs or Plaintiff's decedent, or by an unforeseeable disease or illness, unavoidable accident, or pre-existing and/or unrelated conditions, or natural courses of conditions of Plaintiffs or Plaintiff's decedent, and were independent of any conduct by Answering Defendants.

7. Plaintiffs and Plaintiff's decedent failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

8. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

9. Bextra® is safe when used as directed, was suitable for the purpose for which it was intended, was distributed with adequate and sufficient warnings and Answering Defendants reasonably assumed that their warnings would be read and heeded; therefore, Bextra® is not and was not defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

10. As a prescription pharmaceutical, Bextra® falls within the ambit of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and

Drug Administration. Accordingly, Plaintiffs' claims have been preempted under the Supremacy Clause of the U.S. Constitution.

11. Both Bextra® and Answering Defendants' actions conformed to the state-of-the-art medical and scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

12. Plaintiffs' claims are barred by assumption of the risk.

13. Plaintiffs' claims are barred in whole or in part because Bextra® "provides net benefits for a class of patients" within the meaning of the Restatement (Third) of Torts: Product Liability § 6, Comment f.

14. Plaintiffs' claims are barred in whole or in part by the "learned intermediary" doctrine.

15. The imposition of punitive damages pursuant to current Alabama law violates the Due Process and Equal Protection provisions of U.S. Const. Amend. XIV; to wit, these Answering Defendants have not been given fair notice of the standard of conduct which could subject them to a claim for punitive damages, and have not been given fair notice of the amount of punitive damages that may accompany a finding of liability. Alabama's current laws regarding punitive damages do not serve a rational or legitimate state interest.

16. Plaintiffs' claims for punitive damages violate these Answering Defendants' rights under the Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendments of the Constitution of the United States of America and Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama.

17. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damages awards which arise under the United States Constitution and decisions of the United States Supreme Court including, but not limited to: *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). Further, Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damages, which arise under the Constitution of Alabama, Alabama state statutes, and the decision of Alabama state courts.

18. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

19. Plaintiffs' claims are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

20. If Plaintiffs and Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by operation of nature or other supervening or intervening conduct of persons other than Answering Defendants, and for whose conduct Answering Defendants are not responsible, or with whom Answering Defendants have no legal relation or legal duty to control.

21. If Plaintiffs and Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Bextra® by persons other than Answering Defendants or persons acting on their behalf.

22. Plaintiffs' claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs and Plaintiff's decedent.

23. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Answering Defendants' rights under the United States Constitution.

24. Plaintiffs' claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Plaintiff's decedent did not incur any ascertainable loss as a result of Answering Defendants' conduct.

25. Plaintiffs' claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling packaging, and any advertising of Bextra® complied with the applicable codes, standards and regulations established, adopted or promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

26. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Bextra® were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

27. Plaintiffs' claims must be dismissed because Plaintiffs and Plaintiff's decedent would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

28. Plaintiffs' claims asserted in the Complaint are barred because the utility of Bextra® outweighed its respective risks.

29. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

30. Plaintiffs' and Plaintiff's decedent's damages, if any, are barred or limited by the payments received from collateral sources.

31. The liability of Answering Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' and Plaintiff's decedent's alleged damages, if any, are determined. Answering Defendants seek an adjudication of the percentage of fault of the claimant and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Plaintiff's decedent.

32. Answering Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs and Plaintiffs' decedent with any other defendant or other person or entity.

33. Plaintiffs' claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, the regulations promulgated thereunder, and the United States Constitution, Article IV, clause 2.

34. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act.

35. Plaintiffs' claims asserted in the Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

36. Plaintiffs' claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article IV, clause 2, and the laws of the United States.

37. If Plaintiffs and Plaintiff's decedent have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Answering Defendants and over whom Answering Defendants had no control and for whom Answering Defendants may not be held accountable.

38. Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

JURY DEMAND

Answering Defendants demand a trial by jury on all issues so triable.

WHEREFORE, Answering Defendants respectfully request that this action be dismissed with prejudice and that they be awarded their costs and any other forms of relief to which they may be entitled.



Lawrence B. Clark
Jason Asbell

OF COUNSEL:

BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, P.C.
Wachovia Tower
420 North 20th Street, Suite 1600
Birmingham, Alabama 35203
Telephone: (205) 328-0480
Facsimile (205) 322-8007

Certificate of Service

I hereby certify that on March 17, 2006, a copy of the foregoing was served upon all counsel of record by placing a copy of same in the United States Mail, postage prepaid:

Mr. Jere L. Beasley
Mr. Andy D. Birchfield, Jr.
Mr. Navan Ward, Jr.
Mr. Paul Sizemore
Mr. Gerald B. Taylor, Jr.
BEASLEY, ALLEN CROW, METHVIN, PORTIS & MILES, P.C.
P.O. Box 4160
Montgomery, Alabama 36103-4160

A handwritten signature in black ink, appearing to read "J. Cull", is written over a horizontal line.

OF COUNSEL